

12-19-05

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Express Mail No. EL 989613770 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hyldig-Nielsen, et al.	Docket No: 375461-036US (355414)
Serial No.: 10/782,646	Confirmation No.: 5487
Filed: February 18, 2004	Group Art Unit: 1635
For: <b>COMPOSITIONS AND METHODS FOR MULTIPLEX ANALYSIS OF POLYNUCLEOTIDES</b>	Examiner: Not yet assigned

TRANSMITTAL

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Enclosed are the following documents for filing in the above-referenced patent application:

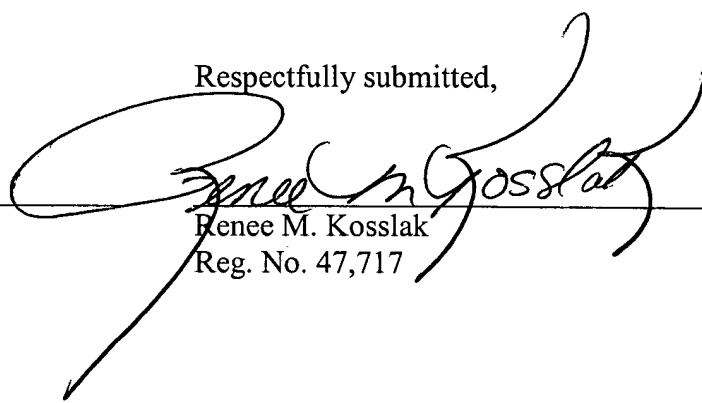
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| <input type="checkbox"/> Fee Transmittal                             | <input type="checkbox"/> Notice of Appeal  |
| <input type="checkbox"/> Amendment/Reply                             | <input type="checkbox"/> Request for Continued Examination                             |
| <input type="checkbox"/> Petition for Extension of Time              | <input type="checkbox"/> Appeal Brief/Reply Brief                                      |
| <input checked="" type="checkbox"/> Information Disclosure Statement | <input checked="" type="checkbox"/> Power of Attorney/Revocation                       |
| <input checked="" type="checkbox"/> Substitute Form PTO 1449         | <input checked="" type="checkbox"/> Limited Authorization to Act of Behalf of Assignee |
| <input checked="" type="checkbox"/> IDS References                   | <input checked="" type="checkbox"/> Change of Attorney Docket Number                   |
| <input type="checkbox"/> International/Foreign Search Report         | <input type="checkbox"/> CRF Diskette  |
| <input type="checkbox"/> Affidavit/Declaration                       | <input type="checkbox"/> CD Disc   |
| <input type="checkbox"/> Terminal Disclaimer                         | <input checked="" type="checkbox"/> Return Receipt Postcard                            |
| <input type="checkbox"/> Other ( <i>itemize</i> )                    | <input type="checkbox"/> Exhibits ( <i>itemize</i> )                                   |
1. 1.

Please direct any inquiries in connection with the above referenced application to the undersigned at telephone number (415) 262-4577.

Respectfully submitted,

Date: December 15, 2005

**DECHERT LLP**  
Customer No. 37509  
Telephone: 650.813.4800  
Facsimile: 650.813.4848



Renee M. Kossiak  
Reg. No. 47,717

12209996.1.BUSINESS



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INFORMATION DISCLOSURE STATEMENT

**Mail Stop Amendment**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR §§ 1.97 and 1.98, Applicant submits herewith patents, publications and/or other information (listed below and/or on the attached Substitute Form PTO 1449) that may be material to the examination of the captioned application, and in respect of which there may be a duty of disclosure as set forth in 37 CFR § 1.56, for consideration and to be made of record in the captioned application by the U.S. Patent and Trademark Office.

1. ☒ In accordance with 37 CFR 1.98, accompanying this Information Disclosure Statement are:

1a. ☒ copies of: (i) each foreign patent listed on the attached Substitute Form PTO 1449; (ii) each publication listed on the attached Substitute Form PTO 1449, or that portion which caused it to be listed, *other than* U.S. patents and U.S. patent application publications; (iii) for each pending unpublished U.S. application, a copy of the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion; and (iv) other information, or

that portion which caused it to be listed herein or on the attached Substitute Form PTO-1449 (37 CFR § 1.98(a)(2)); and/or

1b. ☐ a concise explanation of relevancy, or an English language translation, of non-English language publications listed on the attached Substitute Form PTO-1449 (37 CFR § 1.98(a)(3)(i) & (ii)).

2. ☐ Copies of the documents listed on the attached Substitute Form PTO 1449 that are further identified by asterisks are not enclosed herewith, because the information was previously submitted to, or cited by, the U.S. Patent and Trademark Office in parent application Serial No. \_\_\_\_\_, of which the captioned application claims benefit under 35 U.S.C. § 120, and the Information Disclosure Statement submitted in that parent application complied with paragraphs (a) through (c) of 37 CFR § 1.98 (37 CFR § 1.98(d)).

3. ☒ This Information Disclosure Statement is filed under 37 CFR § 1.97(b):

3a. ☐ within three months of the filing date of a national application other than a continued prosecution application under 37 CFR § 1.53(d);

3b. ☐ within three months of the entry of the national stage as set forth in 37 CFR § 1.491 in an international application;

3c. ☒ before the mailing of a first Office Action on the merits; *or*

3d. ☐ before the mailing of a first Office Action after the filing of a Request for Continued Examination under 37 CFR § 1.114. Accordingly, no certification or fee is required.

4. ☐ This Information Disclosure Statement is filed under CFR § 1.97(c) after the period specified by CFR § 1.97(b), but before the mailing date of any of a final Office Action under 37 CFR § 1.113, a notice of allowance under 37 CFR § 1.311, or an action that otherwise closes prosecution in the application, and is accompanied by one of:

- 4a. ☐ the statement specified in 37 CFR § 1.97(e); *or*
- 4b. ☐ the fee set forth in 37 CFR § 1.17(p).
5. ☐ This Information Disclosure Statement is filed under 37 CFR § 1.97(d) after the period specified by CFR § 1.97(c), but on or before payment of the issue fee, and is accompanied by:
- 5a. ☐ the statement specified in 37 CFR § 1.97(e); *and*
- 5b. ☐ the fee set forth in 37 CFR § 1.17(p).
6. ☐ Certification Statement (*applicable if Item 4a or 5a is checked*)
- 6a. ☐ In accordance with 37 CFR § 1.97(e)(1), the undersigned hereby states that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; *or*
- 6b. ☐ In accordance with 37 CFR § 1.97(e)(2), the undersigned hereby states that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making a reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
7. ☐ Fee Statement and/or Authorization (*applicable if Item 4b or 5b is checked*)
- 7a. ☐ The fee set forth in 37 CFR § 1.17(p) is:
- ☐ enclosed; *or*

☐ to be charged to Dechert LLP Deposit Account No. 50-2778 (Order No. \_\_\_\_\_).

8. ☐ Additional materials (*if applicable*)

8a. ☐ a continuation application under 37 CFR § 1.53(b)(1) is filed concurrently herewith;

8b. ☐ a Request for Continued Examination under 37 CFR § 1.114 is filed concurrently herewith; *or*

8c. ☐ a Petition to Withdraw from issue under 37 CFR § 1.313(c)(2).

As specified in 37 CFR § 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made.

The filing of this Information Disclosure Statement shall not be construed as a representation that no other material information as defined in 37 CFR § 1.56(a) exists.

As specified in 37 CFR § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any information cited herein is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

Moreover, while the patents, publications and/or other information disclosed in this Information Disclosure Statement may be “material” pursuant to 37 CFR § 1.56, the Disclosure is not intended to constitute an admission that any patents, publications and/or other information included or referred to herein is “prior art” to the captioned application unless specifically designated as such.

It is respectfully submitted that this Information Disclosure Statement is in compliance with 37 CFR § 1.98 and MPEP § 609. Accordingly, consideration of the foregoing and prompt

return of a copy of the enclosed Substitute form PTO 1449 with the Examiner's initials in the left column in accordance with MPEP § 609 are respectfully requested.

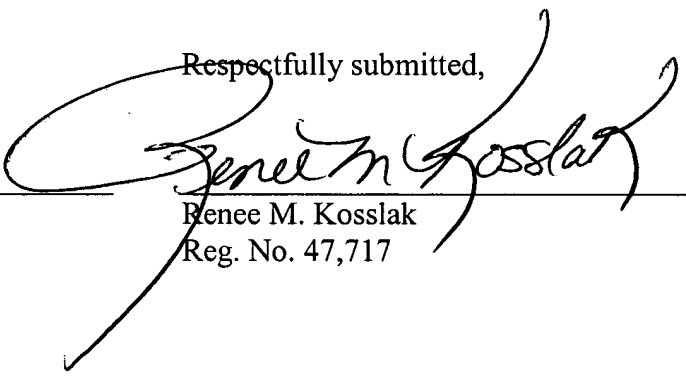
No fees beyond are believed due in connection with this Information Disclosure Statement. However, the Commissioner is authorized to charge any additional required fees, or credit any overpayment, to Dechert LLP Deposit Account No. 50-2778 (**Order No. 375461-036US (355414)**).

Please direct any inquiries in connection with the above referenced application to the undersigned at telephone number (415) 262-4577.

Date: December 15, 2005

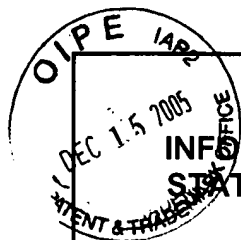
**DECHERT LLP**  
Customer No. 37509  
Telephone: 650.813.4800  
Facsimile: 650.813.4848

Respectfully submitted,



Renee M. Kosslak  
Reg. No. 47,717

12210010.1.BUSINESS



Substitute for form 1449A/PTO  
(Modified)

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

1

of

2

### Complete if Known

Application Number	10/782,646
Filing Date	February 18, 2004
First Named Inventor	HYLDIG-NIELSEN, et al
Art Unit	1635
Examiner Name	Not Yet Assigned
Attorney Docket Number	375461-036US

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	US-6,472,156 B1	10-29-2002	Wittwer et al.	
	A2	US-6,265,166	07-24-2001	Frank-Kamenetskii et al.	
	A3	US-2003/0077608	04-24-2003	Coull et al.	

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document Country Code <sup>2</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	B1	WO 00/18965 A1	04-06-2000	University of Utah Research Foundation		
	B2	WO 92/14845 A1	09-03-1992	Worcester Foundation for Experimental Biology		
	B3	WO 99/42611 A1	08-26-1999	The Secretary of State for the Defense		
	B4	WO 00/56746 A2	09-28-2000	Exiqon A/S		
	B5	WO 01/48190 A2	07-05-2001	Exiqon A/S		
	B6	WO 02/28875 A2	04-11-2002	Cureon A/S		

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	C1	DE SILVA, D., et al., "Monitoring Hybridization During Polymerase Chain Reaction," Journal of Chromatography, Biomedical Applications, April 2000, 3-13, 741(1), Elsevier, Amsterdam, NL	
	C2	BERNARD, P.S., et al., "Homogeneous Multiplex Genotyping of Hemochromatosis Mutations with Fluorescent Hybridization Probes," American Journal of Pathology, October 1998, 1055-1061, 153(4), Philadelphia, PA, US	
	C3	BERNARD, P.S., et al., "Color Multiplexing, Hybridization Probes Using the Apolipoprotein E Locus As A Model System for Genotyping," Analytical Biochemistry, September 10, 1999, 221-228, 273(2), San Diego, CA, US	
	C4	"LightCycler System Real-Time PCR - as flexible as you are," Roche Diagnostics Corporation, 2001, pp. 1-34	
	C5	AFONINA et al., "Efficient Priming of PCR with Short Oligonucleotides Conjugated to a Minor Groove Binder," Nucleic Acids Research, 1997, 2657-2660, 25(13)	
	C6	BONNET et al., "Thermodynamic Basis of the Enhanced Specificity of Structured DNA Probes," Proc. Natl. Acad. Sci. USA, May 1999, 6171-6176, 96	
	C7	ELAYADI et al., "Implications of High-Affinity Hybridization by Locked Nucleic Acid Oligomers for Inhibition of Human Telomerase," Biochemistry, 2002, 9973-9981, 41	
	C8	KOSHKIN et al., "LNA (Locked Nucleic Acid): An RNA Mimic Forming Exceedingly Stable LNA:LNA Duplexes," J. Am. Chem. Soc., 1998, 13252-13253, 120	
	C9	KOSHKIN et al., "Novel Convenient Syntheses of LNA [2.2.1] Bicyclo Nucleosides," Tetrahedron Letter, 1998, 4381-4384, 39	
	C10	KUMAR et al., "The First Analogues of LNA (Locked Nucleic Acids): Phosphorothioate-LNA and 2'-Thio-LNA," Bioorganic & Medicinal Chemistry Letters, 2219-2222, 8	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the complete application form to the USPTO. Time will vary depending on the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449A/PTO (Modified)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/782,646
				Filing Date	February 18, 2004
				First Named Inventor	HYLDIG-NIELSEN, et al
				Art Unit	1635
Examiner Name	Not Yet Assigned				
Sheet	2	of	2	Attorney Docket Number	375461-036US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>	
	C11	MARRAS et al., "Efficiencies of Fluorescence Resonance Energy Transfer and Contact-Mediated Quenching in Oligonucleotide Probes," Nucleic Acids Research, 2002, 1-8, 30(21)		
	C12	SAGHATELIAN et al., "DNA Detection and Signal Amplification Via An Engineered Allosteric Enzyme," J. Am. Chem. Soc., 2003, 344-345, 125		
	C13	SINGH et al., "Universality of LNA-Mediated High-Affinity Nucleic Acid Recognition," Chem. Commun., 1998, pp. 1247-1248		
	C14	STUYVER et al., "Classification of Hepatitis C Viruses Based on Phylogenetic Analysis of the Envelope 1 and Nonstructural 5B Regions and Identification of Five Additional Subtypes," Proc. Natl. Acad. Sci. USA, October 1994, 10134-10138, 91		
	C15	STUYVER et al., "Second-Generation Line Probe Assay for Hepatitis C Virus Genotyping," Journal of Clinical Microbiology, September 1996, 2259-2266, 34(9)		
	C16	TIAN et al., "Solvent Effect on the Triplet Lifetime of Some Rhodamine Dyes," Dyes and Pigments, 1994, 167-174, 26		
	C17	YARON et al., "Intramolecularly Quenched Fluorogenic Substrates for Hydrolytic Enzymes," Analytical Biochemistry, 1979, 228-235, 95		
	C18	ZEIN, "Clinical Significance of Hepatitis C Virus Genotypes," Clinical Microbiology Review, April 2000, 223-235, 13(2)		
	C19	International Search Report for PCT/US2004/004815 dated August 24, 2004.		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.

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